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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/846,565	WINTERS, R. EDWARD	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-8,15,16 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-8, 15, 16, and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments presented in the after-final response filed September 2, 2008, with respect to claims 5-8 and 15-16 have been fully considered and are persuasive. The rejection of Brown (US 6,093,199) in view of Jones (US 6,811,560 B2) with respect to these claims has been withdrawn.

The after final amendment filed September 2, 2008 has been entered. Thus the finality of the office action dated May 29, 2008 has been withdrawn, prosecution is herein reopened. Claims 5-8, 15, 16, and 19 are currently pending. The current action is non-final.

The applicant has argued that Brown (US 6,093,199) is not combinable with Dubrul (US 6,258,115 B1), because Brown discloses a helical wound wire stent and Dubrul discloses a laser cut tube stent, two different stent types. The examiner disagrees. Although Dubrul discloses some embodiments of a cut tube stent (figures 4a, 4b for example), Dubrul discloses alternate embodiments such as shown in figures 2a, 2b, 4c and 4d wire coil stent made from winding a wire around a mandrel, see col.8, lines 34-61. One specific embodiment disclosed by Dubrul is a round wire wound helically to form a tube, having the spacing claimed, see col.8, lines 49-61. This embodiment of Dubrul's stent is helical wound wire similar in design to the Brown helical stent, thus the teachings of Dubrul and Brown are combinable as they refer to the same general field of study, helically wound wire stents for blood vessels.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-8, 15, 16, and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 5 recites the following limitations which are considered new matter: "inserting said hoop and said delivery means into an artery at said target site *having an unsupported aperture size less than said nominal opening size*" and "secondary coil is configured to *urge said target site aperture to said nominal opening size*" emphasis added.

The specification does not support insertion of the hoop into the artery when it is narrowed or occluded (unsupported size *less than* nominal size), instead the specification requires opening of the narrowed or occluded artery *prior to insertion* of the hoop by balloon dilation. Therefore, at the time of hoop insertion, the artery is no longer a size less than nominal size and further would not urge the aperture to a larger nominal size. The specification shows two different methods: the first method including inserting a hoop into an artery that *has not been occluded* (this method is shown in figures 3-5). This method does not require balloon dilation, and further does not insert the hoop at a smaller diameter, since there is no narrowing or occlusion present. This is not the method being claimed, because the claim requires inserting into a lumen *with an occlusion*. The only mention in the specification of an occluded artery is on page 7, lines 19-22 and page 9, lines 15-23 referring to the method shown in figures 6-13. Every figure and recitation of dilation of the occlusion refers to balloon dilation prior to hoop insertion. There is no support for the hoop to do the actual dilation (increasing diameter or urging of vessel

to nominal size). The hoop is only disclosed to radially *support* or *hold* open the vessel, not to force or urge open (holding open and urging open have very different meanings, urging is not the equivalent of holding). Claims 6-8, 15, 16, and 19 depend upon claim 5 and inherit all problems associated with the claim.

Claim 15 also contains the following limitation which is considered new matter: "longitudinal open space" and each recitation of "open space" in the claim. The specification only refers to an open spac*ing*. That is spacing between hoop coils. A longitudinal open space is not supported as the spacing is never referred to be longitudinal in shape, and further never referred to being a single space. It is only referred as an "open spacing" which has different meaning and interpretation than "longitudinal open space". Claim 16 depends upon claim 15 and inherits all problems with the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-8, 15, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul (US 6,258,115 B1, cited previously) in view of Brown (US 6,093,199, cited previously) and Hieshima et al. (US 6,361,558 B1). Dubrul discloses a procedure for opening a coronary artery (carotid or any other blood vessel in the body; thus includes coronary; col.4, lines 46-48; col.5, lines 11-14) having a nominal opening size (fig.1; at location of numeral 10 or 12) adjacent a target having a partial occlusion thereof (fig.1; numeral 13; col.1, lines 16-20)

comprising the steps of determining an artery nominal size (size near 10 and 12 in fig.1), providing a hoop coil stent (stent embodiment referred herein not shown, however disclosed at col.8, lines 49-61) and inserting the hoop stent and delivery means into the artery at the target site (13) having an unsupported aperture size less than the nominal size (size of artery at 13 is smaller than adjacent to 13; see fig.1; example stent shown placed at target site in fig.5b), removing the delivery means (fig.5c shows delivery means removed) such that the hoop stent diameter is larger than the unsupported diameter and the hoop stent is configured to urge the aperture to the nominal size (occlusion 13 shown dilating from fig.5b to fig.5c as the example stent is expanded; discloses urging open or "propping open", col.4, lines 47-49). Dubrul discloses the hoop stent to have an open spacing greater than the rest of the hoop stent spacing placed at a branch vessel to allow flow through the open spacing (col.8, lines 51-59). Dubrul discloses balloon dilation prior to hoop insertion (col.10, lines 7-10).

Dubrul discloses the method substantially as claimed, however discloses the hoop stent to have a secondary coil shape only, and not a primary coil shape. Brown teaches in the same field of hoop stents for placement in blood vessels, the use of a helical stent (30; all figures) having both a primary *and* secondary coil in order to provide increased strength to support the vessel and the ability to delivery at a smaller diameter (over a rod or within a catheter in a linear shape-creating a lower profile with reduced trauma), col.4, lines 49-67; col.3, lines 12-27. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dubrul's method of opening an artery with a hoop stent having a secondary coil, with Brown's teaching of using a primary coil in addition to a secondary coil on hoop stents in order to provide a method that better supports the vessel wall with reduced trauma due to the low

delivery and higher strength of the improved hoop stent. See Neuss (US 5,536,274) as evidence of another example of use of a primary and secondary coil structure on a helical stent for use of holding open a blood vessel (col.6, lines 1-3, 44-48; fig.1, 3).

Dubrul also does not disclose the hoop stent to have a rounded end. Hieshima teaches in the same field of hoop stents (10; see fig.1) for use in blood vessels (abstract), the use of a rounded end (28) in order to reduce trauma during insertion into the body by avoiding sharp edges that may catch on the vessel wall (col.4, lines 18-22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dubrul's method of opening an artery by insertion of a hoop stent, with Hieshima's teaching of placing rounded ends on hoops stents, in order to provide a reduced trauma surgery.

Claims 5-8 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuss (US 5,536,274) in view of Fischell et al. (US 4,768,507). Neuss discloses a procedure substantially as claimed. Neuss discloses determining inserting a preformed hoop stent having the primary (2) and secondary (1) coil shapes claimed (fig.1, 3; col.6, lines 44-47), the hoop having a rounded end (seen in fig.11a) and memory properties, inserting the hoop stent by a delivery means (14, 16, or 19; fig.11a-11e) into an artery and removing the delivery means so that the hoop supports the artery in the secondary coil shape (keeping an organ pathway open, col.6, lines 1-3). Neuss discloses the method substantially as claimed by placement of a hoop stent into a vessel to support the vessel, however Neuss does not disclose whether or not the vessel is occluded (placement of the stent into an occluded vessel, such that the stent opens the vessel). Placement of stents in occluded or narrowed areas of vessels is well known in the art

and one of the main purposes of stents. Fischell teaches in the same field of hoop stents, the use of helical type hoops stents in areas where occlusions or narrowing is present (fig.1a) in order to widen the vessel wall to its normal size to provide optimal blood flow (fig.2) and prevent restenosis (col.2, lines 1-3, 53-59; col.3, lines 22-46; col.4, lines 57-64). Fischell does this by balloon dilation to expand the lumen and by expanding the lumen with the hoop stent (col.2, lines 1-3, 56-59; col.3, lines 25-28). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Neuss's method of implanting a hoop stent with the shape claimed into a vessel to support the vessel, with Fischell's teaching of placement hoops stents similar to Neuss's into occluded or narrowed vessels in order to provide a method that provides benefit to occluded vessels as well, widening the area for flow and preventing restenosis.

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hieshima et al. (US 6,361,558 B1) in view of Brown (US 6,093,199, cited previously). Hieshima discloses a procedure for opening a coronary artery (any blood vessel in the body; thus includes coronary;col.3, lines 26-29) having a nominal opening size (normal size, not narrowed) adjacent a target having a partial occlusion thereof (narrowed or occluded site; col.3, lines 26-29; col.2, lines 14-16) comprising the steps of determining an artery nominal size, providing a hoop coil stent (10; fig.1) having memory and a rounded end (28), and inserting the hoop stent and delivery means into the artery at the target site (fig.4 or 9 for example) having an unsupported aperture size less than the nominal size, removing the delivery means (fig.8, 9) such that the hoop stent diameter is larger than the unsupported diameter and the hoop stent is configured to

urge the aperture to the nominal size (opening narrowed vessels, col.3, lines 26-30; col.4 line 66-col.5 line 5; col.6, lines 3-9).

Hieshima discloses the method substantially as claimed, however discloses the hoop stent to have a secondary coil shape only, and not a primary coil shape. Brown teaches in the same field of hoop stents for placement in blood vessels, the use of a helical stent (30; all figures) having both a primary *and* secondary coil in order to provide increased strength to support the vessel and the ability to delivery at a smaller diameter (over a rod or within a catheter in a linear shape-creating a lower profile with reduced trauma), col.4, lines 49-67; col.3, lines 12-27. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Hieshima's method of opening an artery with a hoop stent having a secondary coil, with Brown's teaching of using a primary coil in addition to a secondary coil on hoop stents in order to provide a method that better supports the vessel wall with reduced trauma due to the low delivery and higher strength of the improved hoop stent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738